REMARKS

I. PRELIMINARY REMARKS

Claims 7, 28 and 43 have been amended. Claims 36, 41 and 42 have been canceled. Claims 47-53 have been added. Claims 7-12, 28-35, 37-40 and 43-53 remain in the application. Claims 12 and 29 have been withdrawn from consideration. Reexamination and reconsideration of the application, as amended, are respectfully requested.

II. BRIEF DESCRIPTION OF EXEMPLARY EMBODIMENTS

The present inventions, as defined by the claims, are directed generally to surgical systems and apparatus that may be used to stimulate tissue. Referring to Figures 29-32, the exemplary stimulation and sensing probe 616 includes a suction device 618 that carries one or more tissue stimulation elements 604. Such stimulation elements 604 may be for tissue stimulation, and to sense electrical activity in tissue. [Specification at, for example, page 37, line 21 to page 38, line 3.] The tissue stimulation elements 604 are also too small to form a transmural lesion in myocardial tissue. [Specification at, for example, page 34, lines 17-23 and page 29, lines 21-33.] The suction device 618 illustrated in Figures 29-32 is also devoid of any apparatus that is capable of forming a transmural lesion in myocardial tissue.

III. REJECTION UNDER 35 U.S.C. § 112

A. The Rejection

Claims 7-11 and 28-46 have been rejected under 35 U.S.C. § 112, first paragraph, as purportedly failing to comply with the enablement requirement. More specifically, the basis for the rejection appears to be that the present specification (1)

did not provide the "threshold size" at which stimulation elements will not be able to form a transmural myocardial lesion and (2) that there are stimulation elements that are not capable of forming a transmural lesion in myocardial tissue in one "modality," but are capable of forming a transmural lesion in myocardial tissue in another.[1]

As claims 36, 41 and 42 have been canceled, the rejection thereof under 35 U.S.C. § 112 has been rendered moot. The rejection of the remaining claims under 35 U.S.C. § 112, first paragraph, is respectfully traversed. Reconsideration thereof is respectfully requested.

B. Discussion

With respect to the first basis for the "enablement" rejection, the test for determining whether or not an application meets the enablement requirement is, quite simply, whether or not the application enables a person skilled in the art to ***make and use*** the claimed invention without undue experimentation. [MPEP § 2164.01.] The present application provides specific examples of stimulation elements that are too small to form a transmural myocardial lesion, including sizes, shapes and materials, as well as specific examples of how such stimulation element may be made. [See, *e.g.*, Figures 31-32; page 34, lines 17-23; and page 29, lines 21-33.] The present application also discloses how to use this aspect of the claimed inventions. [See, *e.g.*, page 37, line 21 to page 38, line 3.] Thus, one of ordinary skill in the art would be able to ***make and use*** the claimed invention. The enablement requirement requires no more.

Additionally, to the extent that the Examiner has taken Official Notice that the stimulation elements which the specification describes as being "too small to form transmural myocardial lesions" can, in fact, form transmural myocardial lesions, applicant hereby traverses and requests that the Examiner provide an affidavit in accordance with MPEP § 2144.03 and 37 C.F.R. § 1.104(d)(2). The affidavit should set forth the facts upon which the Examiner's conclusions concerning the sizes of

[1] Applicant notes for the record that means-plus-function element in independent claim 43 does not use the phrase "too small," as asserted in the Office Action.

stimulation elements that are capable (and not capable) of forming transmural myocardial lesions are based.

Turning to the second basis for the "enablement" rejection, i.e. the different "modality" basis, applicant notes that independent claims 7, 28 and 43 do not equivocate based on "modality." Instead, claims 7 and 28 specifically call for "a tissue stimulation element that is too small to form a transmural lesion in myocardial tissue." ***Period***. Claim 43 specifically calls for the function of "stimulating myocardial tissue without forming a transmural lesion in the myocardial tissue." ***Period***. If the Examiner is aware of some "modality" in which the exemplary stimulation elements that the specification describes as being "too small to form transmural myocardial lesions" are, in fact, able to form transmural myocardial lesions, applicant hereby requests that this "modality" also be discussed in the aforementioned affidavit.

As illustrated above, the aspects of the claimed inventions identified in the Office Action are clearly enabled and, accordingly, the rejection of claims 7-11, 28-35, 37-40 and 43-46 under 35 U.S.C. § 112, first paragraph, should be withdrawn.

IV. PRIOR ART REJECTIONS

A. The Rejections

Claims 7-11, 28-30, 36 and 40-46 have been rejected under 35 U.S.C. § 102 as being anticipated by the U.S. Patent No. 6,849,075 to Bortolero ("the Bortolero '075 patent"). Claims 31-39 have been rejected under 35 U.S.C. § 103 as being unpatentable over the Bortolero '075 patent. As claims 36, 41 and 42 have been canceled, the rejection thereof under 35 U.S.C. § 102 has been rendered moot. The rejections of the remaining claims under 35 U.S.C. § 102 and 103 are respectfully traversed with respect to the claims as amended above. Reconsideration thereof is respectfully requested.

B. Discussion Concerning Claims 7-11, 28-35 and 37-40

Independent claims 7 and 28 call for respective combinations of elements including, *inter alia*, "a suction device" and "a tissue stimulation element that is ***too small to form a transmural lesion*** in myocardial tissue on the suction device." Independent claims 7 and 28 also specify that the "suction device ***does not carry an apparatus that is capable*** of forming a transmural lesion in myocardial tissue." The respective combinations defined by claims 8-11 and 37-40 include, *inter alia*, the elements recited in claim 7, and the respective combinations defined by claims 30-35 include, *inter alia*, the elements recited in claim 28.

The Bortolero '075 patent fails to teach or suggest the claimed combinations. For example, and referring to Figure 2, the Bortolero '075 patent discloses a tissue contacting member 102 with suction apertures 212 and sensors 214. In contrast to the claimed combinations however, the device illustrated in Figure 2 is an "ablation device" and, accordingly, carries an ablation member 210 that is specifically configured to form transmural lesions. [Column 11, lines 39-50.] With respect to the ablation device illustrated in Figure 4, the Office Action appears to have taken the position that the ***ablation*** member 410 (i.e. the RF coil) corresponds to the claimed "tissue stimulation element." Not only is there no reasonable interpretation of the phrase "too small to form a transmural lesion in myocardial tissue" that would read on the ablation member 410, nothing in the Bortolero '075 patent even remotely indicates that it is not capable of forming a transmural lesion in myocardial tissue.

As the Bortolero '075 patent fails to teach or suggest each and every element of the respective combinations recited in independent claims 7 and 28, applicant respectfully submits that claims 7-11, 28 and 30 are patentable thereover and that the rejection under 35 U.S.C. § 102 should be withdrawn.

Additionally, in view of the fact that the Office Action did not provide any rationale for modifying the Bortolero devices in such a manner that the inventions defined by independent claims 7 and 28 would have been realized, applicant respectfully submits that claims 31-35 and 37-39 are patentable for at least the same reasons as

independent claims 7 and 28 and that the rejection of claims 31-35 and 37-39 under 35 103 should also be withdrawn.

C. Discussion Concerning Claims 43-46

Independent claim 43 calls for a combination of elements including, *inter alia*, "a suction device" and "tissue stimulation means, carried by the suction device, for stimulating myocardial tissue without forming a transmural lesion in the myocardial tissue." Independent claim 43 further specifies that "the suction device does not carry an apparatus that is capable of forming a transmural lesion in myocardial tissue." The combinations defined by claims 44-46 include, *inter alia*, the elements recited in claim 43.

The Bortolero '075 patent fails to teach or suggest the claimed combinations. For example, and as discussed at length in the preceding section, the Bortolero '075 patent does not teach or suggest a "suction device [that] does not carry an apparatus that is capable of forming a transmural lesion in myocardial tissue."

As the Bortolero '075 patent fails to teach or suggest each and every element of the combination recited in independent claim 43, applicant respectfully submits that claims 43-46 are patentable thereover and that the rejection under 35 U.S.C. § 102 should be withdrawn.

V. NEWLY PRESENTED CLAIMS 47-53

Newly presented independent claim 47 calls for a combination of elements comprising "a suction tube," "a suction device," "a tissue stimulation element on the suction device" and "a signal line that is connected to the tissue stimulation element and extends through the suction tube." Applicant respectfully submits that the Bortolero '075 patent fails to teach or suggest such a combination and that claims 47-53 are patentable thereover.

VI. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

Respectfully submitted,

May 4, 2006
Date

/Craig A. Slavin/
Craig A. Slavin
Reg. No. 35,362
Attorney for Applicant

Henricks, Slavin & Holmes LLP
840 Apollo Street, Suite 200
El Segundo, CA 90245
(310) 563-1458
(310) 563-1460 (Facsimile)